

For some readers, this will be the last paper issue of **Bandolier** they will see. Changes to funding arrangements mean that if you want a paper copy, you, or your institution, will have to take out a subscription. How to do this, and the substantial cost savings for bulk orders, are outlined in the centre pages of this issue.

## Onwards and upwards

This does not mean that **Bandolier** has finished. Far from it. The monthly paper version will continue as now, and those who subscribe will have it on their desk every month. It may even be possible to add to what you get, though ideas for that are in the early stages.

The Internet version will continue as well, though you will only be able to download free PDF versions of the paper issue three months or so in arrears. The expansion of electronic **Bandolier** over the next few months will include expansions to the section on gout, and update and expansion of pain and arthritis sections.

## Reflections

Why 101? Nothing to do with dalmatians, just the way it turned out. **Bandolier** still feels slightly bemused after 101 hand-to-mouth issues over getting on for nine years. Someone once told us that everyone knew everything about evidence, and we should concentrate on other things. That was about issue 36, yet we find ourselves still learning.

## What works, and problems

Doing better is what it all comes down to. This issue therefore is largely devoted to topics about doing better (recognising that treatment protocols or care pathways give better results) and not doing badly (recognising the problems of adverse drug reactions), plus a few thought provoking topics and books.

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*The views expressed in **Bandolier** are those of the authors, and are not necessarily those of the NHSE*

## TREATMENT PROTOCOL EFFECTIVENESS

The unique biology of the patient, with their special circumstances, drives diagnosis and treatment. Yet individuals are often sufficiently similar one to another to make a treatment protocol, based on evidence, seem worthwhile. Even if it ensures that nothing important is missed, it should reduce error and might improve results. To that end treatment protocols, or clinical pathways, critical pathways or care paths have been developed and are used.

Do they deliver? This is not just being precious about evidence, but has real importance. Treatment protocols often require more front-end resources. Where the biggest constraint is one of capacity, as in the NHS right now, we need to know that professionals' time is likely to be used to the best advantage.

Treatment protocols are often used in hospital, where the advantage might be reduced length of stay. Where beds are restricted or waiting times long, more throughput could be a major benefit.

So **Bandolier** has been looking for evidence from randomised trials that treatment protocols deliver the goods. What follows is not an exhaustive systematic review, but a taster of papers we found. There are seven examples, in different situations with different goals and outcomes, all in secondary care. For each we give a brief outline of the method and results. The main outcome in most is length of hospital stay.

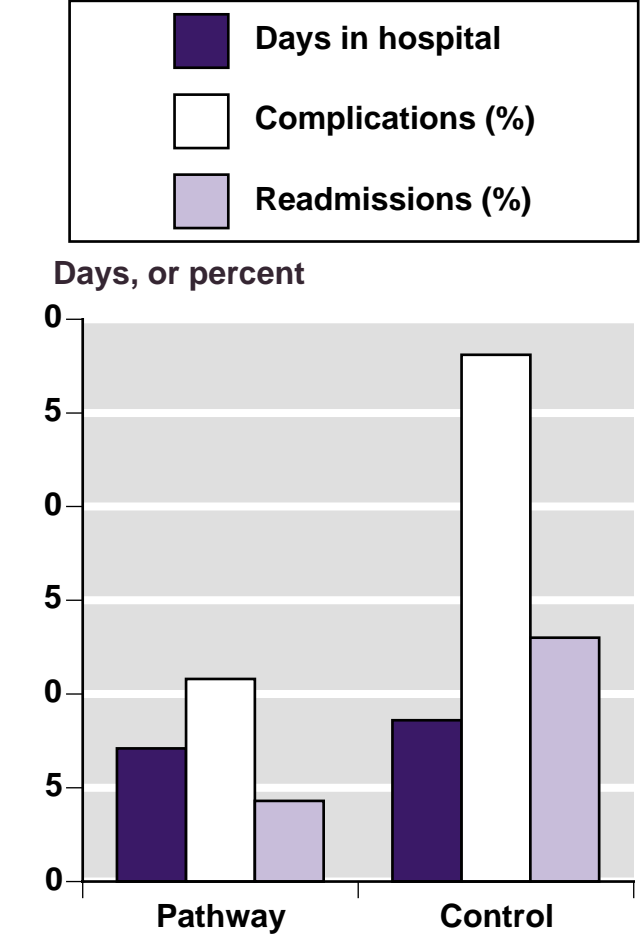
## Hip and knee replacement [1]

This study in Australia randomised patients admitted for standard hip or knee replacement to:

- ♦ standard reactive treatment where the treating team responded to the will and condition of the patient in providing postoperative care
- ♦ proactive treatment in a care pathway where specific goals were set each day for the patient and treating team, using a special written protocol listing milestones to be achieved, tests ordered, and daily tasks for patient and team members.

The main outcome was length of stay, but others collected included complications (wound infection, chest infection, deep vein thrombosis, for instance) and readmission rates.

**Figure 1: Outcomes in knee and hip replacement**



**Results**

The 92 patients randomised to the pathway and 71 to control were similar in age, weight and co-morbid conditions. Those treated in the pathway sat out of bed and were ambulant earlier, and were discharged after 7.1 rather than 8.6 days (Figure 1). There were fewer complications, and the proportion readmitted within three months was 4% for the pathway, against 13% for controls.

**Comment**

Reduced length of stay did not increase the complication rate. This might have been a concern, perhaps, about whether the patients were having too little time in hospital with more complications and higher readmissions later on. Readmissions did not increase, but fell. No costs or resource allocation are given in the paper, but there is no indication that this care pathway should cost more to provide better quality of care.

**Fractured neck of femur [2]**

Another Australian study randomised (but by date of birth) uncomplicated patients with fractured neck of femur to usual care or to a clinical pathway. The main components of this pathway included an admission information checklist, specific pathway documentation specifying responsibilities and time, with a discharge package, and with discharge planning begun on admission.

**Results**

The 55 patients randomised to the pathway and 56 to control were similar in age and weight. Those treated in the pathway had earlier mobilisation, and were discharged after 6.6 rather than 8.0 days. There were fewer in-hospital complications (24% versus 26%), and the proportion readmitted within one month was 4% for the pathway, against 11% for controls, though these last two were not statistically different.

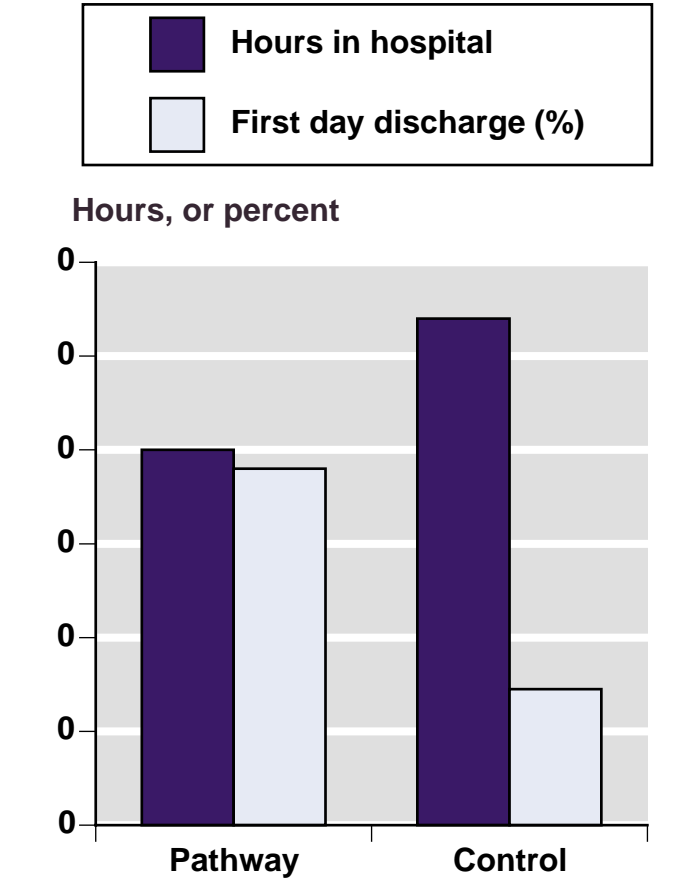
**Comment**

This was a small study in a unit already operating with an on-site rehabilitation unit and quite short background length of stay. Patients included those who, on admission, were confused (40%), had a co-morbid condition (33%) or who did not speak English (26%), so that the population studied was not over-selected. Their mean age was 83 years.

**Inpatient asthma management [3]**

In this study from Johns Hopkins a paediatric multidisciplinary team combined to create the care pathway, plus a weaning protocol designed for asthma patients between two and 18 years of age. Patients being admitted with a primary diagnosis of asthma exacerbation were randomised to a bed on the intervention unit (in which staff had been trained in the pathway) or a control unit in which they received standard care.

**Figure 2: Outcomes in asthma management in children**



## Results

There were 55 patients treated using the clinical pathway, and 55 usual care controls. They were similar apart from clinical path children being slightly older. The duration of hospital stay was significantly shorter using the clinical pathway (40 versus 54 hours, Figure 2) with a larger percentage discharged in the first day (38% versus 15%). The pathway also resulted in less use of  $\beta$ -agonists. The average cost was almost US\$1,000 per patient lower for patients in the clinical pathway.

## Comment

A particularly detailed and interesting paper, this. It shows shorter stay, better outcomes, and lower cost. One problem was that only a quarter of eligible patients could be enrolled in the study because of bed shortages.

## Community-acquired pneumonia [4]

A critical pathway for treating patients had three main components: use of a clinical prediction rule to assist admission decisions, treatment with levofloxacin (a fluoroquinolone antibiotic with good oral bioavailability and broad antimicrobial activity), and practice guidelines for care of inpatients. Nineteen hospitals were randomised to continue conventional management or implement the critical pathway.

## Results

Over six months 1,743 patients were evaluated. Hospitals using the critical pathway had an 18% reduction in the admission of low-risk patients (31% versus 49% of admissions were low risk). Those treated in hospitals using the pathway spent 1.7 fewer days in hospital (5.0 versus 6.7 days), despite having more severe disease. Patients at hospitals implementing the pathway were also much more likely to be treated with a single antibiotic (64% versus 27%). There was no difference in the rate of adverse clinical outcomes (intensive care admission, mortality, readmission, complication), or quality of life indicators.

## Comment

Combining the lower admission rate and reduced hospital stay, this care pathway, the authors computed a reduced cost of treating each case of US\$1,700. This was at no reduction in quality of care or clinical outcomes.

## Stroke rehabilitation [5]

An integrated care pathway based on evidence of best practice and professional standards was developed and coordinated by an experienced nurse in London. Eligible patients were those with persistent impairment within two weeks of the event. Exclusions were those with severe premorbid conditions or cognitive disability, or who had only mild deficits not needing rehabilitation. The stroke rehabilitation unit had two independent teams of carers, and the care pathway was introduced in one of them.

## Results

There were 76 patients in each group, with a mean age of 75 years and no difference at baseline. There was no difference between the groups in outcomes or length of stay, institutional admission, or mortality.

## Comment

This negative result could, of course, be due to the fact that care was already so good that it could not be bettered. The average length of stay was about 50 days, but the standard deviation was a huge 20 days, indicating the large variations between patients. This may have been influenced by issues other than those in the study. And there could have been cross-over between the two teams. Whatever, the additional cost of a coordinating nurse made the pathway more expensive at no benefit.

## Use of laboratory tests [6]

Prospective randomised studies of patients undergoing elective surgery or acute medical admissions using clinical pathways were examined for use of laboratory tests in this Australian study.

## Results

In the elective surgery study of 224 patients, use of laboratory tests was reduced by about 70% using the care pathway (1 versus 3 tests per patient for hernias, 3 versus 7 tests per patient for cholecystectomy). For acute medical admissions, there were 12 versus 16 tests per patient using the care pathway. These were mainly haematology and clinical chemistry tests. Estimated cost reductions were of the order of A\$68 (£26) per patient.

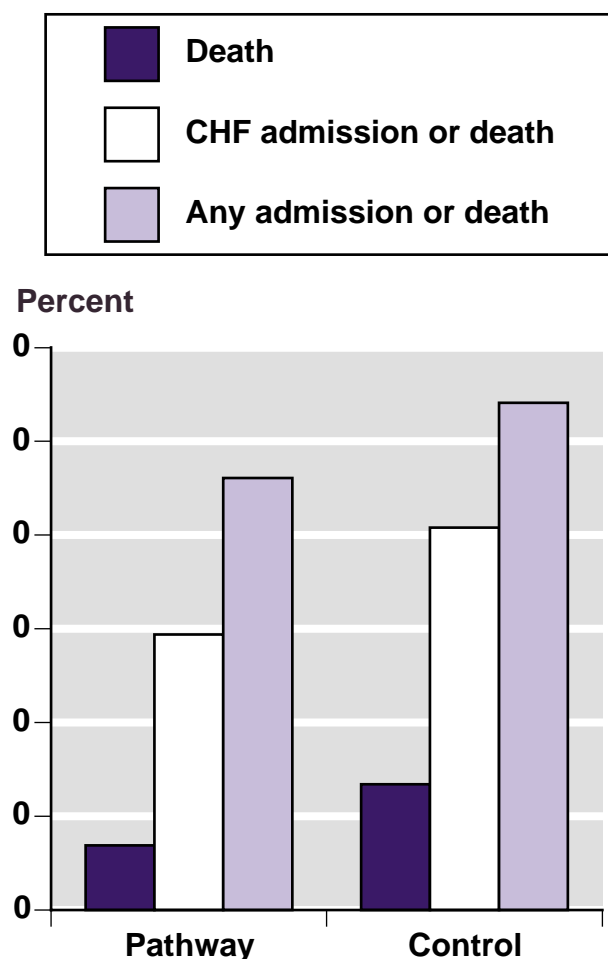
## Comment

There was no suggestion that patient care was in any way impaired by this reduction in laboratory testing. As laboratory tests have often been shown to be over-used, this outcome is a beneficial effect from using a care pathway.

## Heart failure [7]

This randomised study from Johns Hopkins concerned patients at high risk of coronary heart failure readmission. This was defined by the presence of one or more of a rather long list that included age over 70 years, low left ventricular ejection fraction, at least one admission for heart failure in the previous year. An intervention team involved a telephone nurse coordinator, a heart failure nurse, heart failure cardiologist and the patient's primary physician. The cardiologist designed and documented a treatment plan for all study patients before randomisation and saw patients at baseline and after six months. The primary care physician delivered the interventions and looked after all non heart failure problems. The heart failure nurse visited patients on a monthly basis, and the telephone coordinator also kept in contact. In the usual care control group the cardiologist's plan was documented without further intervention.

**Figure 3: Outcomes in heart failure management in the community**



## Results

Two hundred patients were enrolled, and the two groups were similar at baseline. There were fewer heart failure hospital admissions or death over six months using the care pathway (49% versus 73%; Figure 3). Patients in the care pathway group were more likely to hit targets of treatment (weight, diet, vasodilators), and have stable or improved symptoms. Inpatient and outpatient resource use had similar costs, though the care pathway group tended to have lower costs and shorter lengths of stay.

## Comment

For every 10 patients treated in the care pathway, one fewer would have died or had a hospital admission for heart failure compared with usual care. Better quality was delivered at the same cost.

## Overall comment

Some of the seven studies were of extremely high quality, particularly those from Johns Hopkins. The studies probably do not constitute the world literature on randomised studies of care pathways or use of treatment protocols. For instance, *Bandolier's* Internet migraine site describes a tyrial of treatment strategies for migraine. But these studies of care pathways do demonstrate a general consistency in delivering better care, or lower costs, or both.

When the system in which we work is constrained by lack of capacity, beds, or professionals, or both, then interventions that reduce bed stay are especially valued. When they also deliver better standards of care, and at lower costs, then they become imperative.

Nor did the design of these pathways require rocket science. They usually involved several disciplines working together to design written protocols based on evidence, experience, and guidelines. What is missing so far is similar evidence on the use of treatment protocols wholly in primary care. The evidence in heart failure management of complicated patients in primary care [7] is that care pathways are effective here too, but we failed to find other evidence. Perhaps we looked in the wrong place.

## References:

- 1 MM Dowsey et al. Clinical pathways in hip and knee arthroplasty: a prospective randomised controlled study. *Medical Journal of Australia* 1999 170: Kr-62.
- 2 PF Choong et al. Clinical pathway for fractured neck of femur: a prospective, controlled study. *Medical Journal of Australia* 2000 172: 423-427.
- 3 KB Johnson et al. Effectiveness of a clinical pathway for inpatient asthma management. *Pediatrics* 2000 106: 1006-1012.
- 4 TJ Marrie et al. A controlled trial of a critical pathway for treatment of community-acquired pneumonia. *JAMA* 2000 283: 749-755.
- 5 D Sulch et al. Randomized controlled trial of integrated (managed) care pathway for stroke rehabilitation. *Stroke* 2000 31: 1929-1934.
- 6 N Board et al. Use of pathology services in re-engineered clinical pathways. *Journal of Quality in Clinical Practice* 2000 20: 24-29.
- 7 EK Kasper. A randomized trial of the efficacy of multidisciplinary care in heart failure outpatients at high risk of hospital readmission. *Journal of the American College of Cardiology* 2002 39: 471-480.

## WORLD DRUG REPORT

Discussions about the problems of drug abuse are often characterised more by feelings and beliefs than by facts. Facts are really important. For instance, the global production of opium in 1999 amounted to just under 6,000 tonnes, and global heroin seizures amounted to 30 tonnes: that is equivalent to 30 billion 10 mg doses of heroin, and that's just the amount seized by the authorities. Cocaine seizures in 1997/8 amounted to about 400 tonnes.

The report of the UN office for Drug Control and Crime Prevention is a must read document [1]. Although it is 180 pages long it is downloadable from the Internet (though at 16 Mbytes it might take some time). It covers production, trafficking and consumption, and epidemiology, prevention and treatment, and much else. The accumulation of many facts about drug abuse in one place is remarkable, and the information contained in it amazingly detailed. An important document, and all of us should thank the governments of Italy and Sweden for paying for it.

World Drug Report 2000. Oxford University Press, Oxford, 2000 ([www.undcp.org/world\\_drug\\_report.html](http://www.undcp.org/world_drug_report.html)) ISBN 92-1-101027-6.

# ADVERSE DRUG REACTIONS

Adverse drug events or reactions (for convenience, ADR) have important consequences for individuals and organisations (**Bandolier 28**). In-hospital ADRs have been ranked as the fourth to sixth most common cause of death in the USA, based on a meta-analysis of only North American studies [1]. We now have two more systematic reviews of the world literature [2,3] which confirm the size of the problem and provide some insights about what to look for.

## Beijer & Blaey [2]

This Dutch study looked for studies relating hospital admission to adverse drug reaction. Excluding papers about drug and alcohol abuse, and drug-related problems during hospital stay, they were left with 68 studies. They used a WHO definition of ADR that excluded therapeutic failure, intentional and accidental poisoning, and drug abuse.

### Results

There were 6,000 ADR-related admissions in a total of 124,000, giving an overall rate of 4.9%, but with large inter-study variation. Almost all of the variation was found in small studies (especially those with just a few hundred patients), with more consistent results in larger studies. The variation could be related just to size, or to special circumstances examined in particular studies.

Subgroup analysis looked at elderly versus non-elderly, (over 65 was the usual criterion). Here the ADR admission rate was 16.6%, compared with 4.1% in younger people. Analysis by condition or medicine was not possible, but year of publication and type of hospital made no difference.

The authors attempt to calculate what the cost was to the Dutch healthcare system in 1998, and came up with the range of Euro186 million to Euro430 million a year. This is based on estimates that a significant proportion of ADR-related admissions in the elderly are preventable.

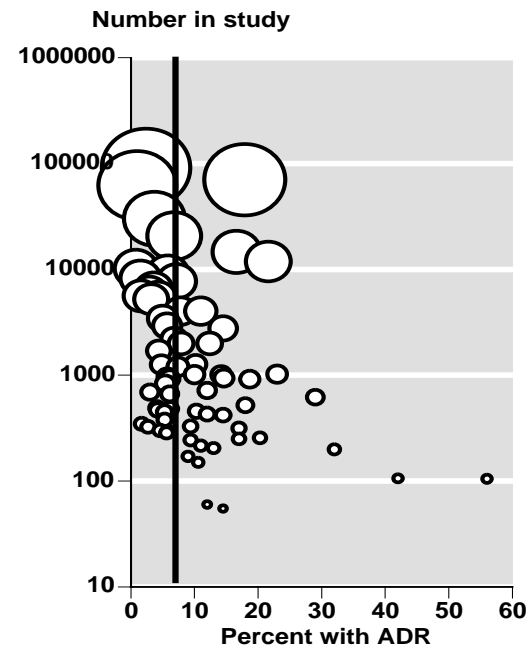
## Wiffen et al [3]

The Oxford study (available as a PDF on the **Bandolier** Internet site) used a similar if wider search strategy looking for:

- ◆ Hospital medical record review whilst patient was in hospital or later review
- ◆ Follow-up survey after release from hospital
- ◆ Case-control, cohort
- ◆ Sample of patients versus all patients with ADRs

Primarily the ADR rate was the key outcome, rather than admissions from ADR, though the ADR rate could be the proportion of patients or admissions. Admission because of an ADR and ADR whilst in hospital were also examined separately. Several prespecified sensitivity analyses were defined.

**Figure 1: ADR rate in studies of different sizes. Vertical line is overall average of 6.7%**



### Results

There were 69 unique studies with evaluable data on 412,000 patients, with an overall ADR rate of 6.7%. Of the 69 studies, 54 were prospective with an ADR rate of 5.5% (193,000 subjects) and 15 were retrospective with an ADR rate of 7.7% (220,000 subjects). Larger studies tended to have lower ADR rates than small studies (Figure 1).

Neither geographical setting nor publication before or after 1985 made much difference, except when clinical setting was added (Table 1). Studies in general medicine after 1985 had a lower ADR rate than those before (3% versus 9%), and those in older people had a higher rate in post-1985 studies (20% versus 4%). Adverse drug reactions were also examined by specialist clinical setting (cancer, emergency departments, for instance) and with specific classes of medicines, and by gender and culture. ADR rates in in-patients and admissions with ADRs were similar.

Several studies examined the interaction between age and number of medicines taken. Older age, and increasing numbers of medicines, especially in women, were associated with ADR rates of between 20% and 50%.

**Table 1: ADR rates with specialty and age of study**

Speciality	Pre/Post 1985	No of subjects	ADR rate % (95% CI)
General medicine	Pre	60401	8.5 (8.2-8.7)
General medicine	Post	243803	2.9 (2.8-3.0)
Geriatric	Pre	11212	4.3 (3.9-4.7)
Geriatric	Post	3488	20 (19-21)
Paediatric	Pre	469	4.2 (2.4-6.0)
Paediatric	Post	837	3.1 (1.9-4.3)



## UK burden

Calculating from the number of accident and emergency visits and inpatient days, the rates of ADR likely from UK, European and US studies, and average stays, the estimate for the burden on the UK NHS was equivalent to about 15-20 400-bed hospitals. This would consume about 4% of available bed-days and cost about £380 million.

## Comment

Both studies also examine the evidence on methods, like computer monitoring or decision aids that can help reduce ADR rates (**Bandolier** 73). Estimates in both studies were that medication errors can be substantially reduced by us-

ing computer systems. When lack of capacity is a major constraint on delivery of healthcare, avoiding ADRs would, together with reducing hospital-acquired infections, be a major contribution to making things better, and would probably be cost saving if introduced.

### References:

- 1 Lazarou J et al. Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies. JAMA 1998; 279(15):1200-05.
- 2 HJ Beijer, CJ de Blaey. Hospitalisations caused by adverse drug reactions (ADR): a meta-analysis of observational studies. Pharmacy World & Science 2002 24: 46-54.
- 3 PJ Wiffen et al. Adverse drug reactions in hospital patients: a systematic review of the prospective and retrospective studies. Bandolier Extra, June 2002, [www/jr2.ox.ac.uk/bandolier/estra.html](http://www/jr2.ox.ac.uk/bandolier/estra.html)

## FRAGMMENT SCORE (SIC) FOR PRESSURE ULCERS

Pressure ulcers are costly and unpleasant, and much effort goes in to avoiding them. Perhaps useful is a new risk prediction scale [1] that can be used by nurses at the bedside.

## Study

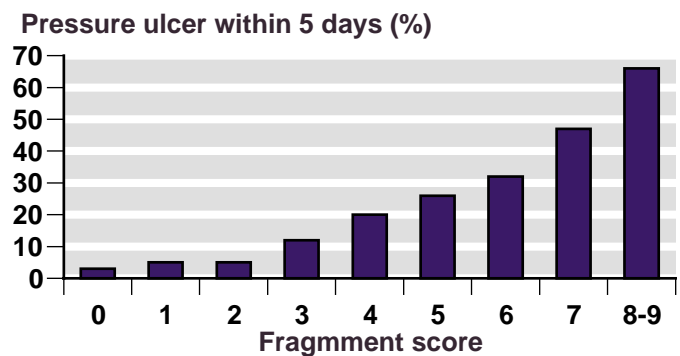
This study from Geneva set out to use baseline predictors for development of pressure ulcers. Possible predictors examined were from commonly used scales (Norton, Braden), potential predictors requiring access to medical records or depending on medical decisions.

Baseline assessments were made on admission and twice weekly follow up for up to three weeks, by specially trained research nurses. Analysis set out to link possible predictors with outcome of pressure ulcer developing within five days, and to create a scoring system based on strong predictors.

## Results

Studied were 1,200 patients admitted to medical and surgical wards (including orthopaedics and neurosurgery), and intensive care. There were 356 new pressure ulcers (34/1,000 patient days) in 182 patients. First pressure ulcers occurred

**Figure 1: Development of pressure ulcer with different Fragmmment scores**



in 170 patients (20/1,000 patient days), and 129 first pressure ulcers developed within five days. This was the main outcome for developing the assessment scale.

Four items were associated with pressure ulcer development, and used to create the Fragmmment scale (friction/shear, age, mobility, mental status; Table 1). Development of pressure ulcer within five days was related to higher scores (Figure 1). Patients with scores of 3 or less made up 80% of the sample, those with scores of 4-6 15% and those with scores of 7-10 5%. The predictive performance of the score seemed to be similar for men and women, with different ages, for medical and surgical patients on different wards, and with nursing workload.

## Comment

This paper nicely describes the development of a simple bedside scoring system to predict the development of a pressure ulcer within five days in an acute setting. It did better than conventional scoring systems. Though it was developed, it was not tested, and independent testing in different contexts would help cement its utility and reliability. It is a super paper, full of much more material than is available here, and shows how high quality nursing research can be carried out.

### References:

- 1 TV Perneger et al. Screening for pressure ulcer risk in an acute care hospital: development of a brief bedside scale. J Clin Epidemiol 2002 55: 498-504.

**Table 1: Components of the Fragmmment score**

Feature	Description	Score
Friction/shear	No problem	0
	Potential problem	1
	Clear problem	2
Age	16-59	0
	60-69	1
	70-79	2
	80-90	3
	90-96	4
Mobility	Full/slight limitation	0
	Very limited	1
	Immobile	2
Mental state	Alert/apathetic	0
	Confused	1
	Stuporous	2

# ARE MY PATIENTS LIKE THIS?

One of the questions we are supposed to ask when interpreting the results of randomised trials into clinical practice is whether the patients in the trial are like our patients? That may be a relatively simple judgement, or it might be rather more difficult.

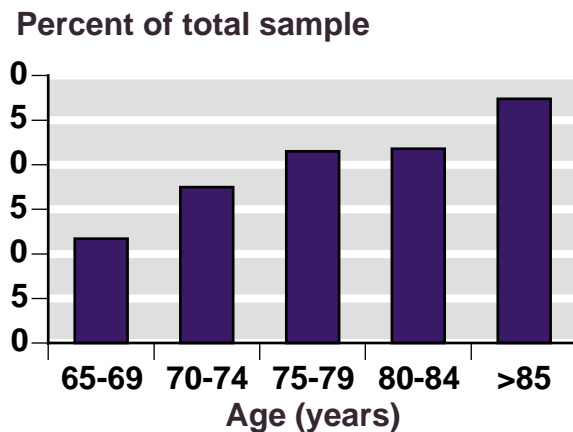
Especially in the elderly the presence of age-related changes, plus the likely presence of other conditions makes it all a bit complicated. For instance, is a 65 year old patient with heart failure likely to be the same as the 85 year old? A large study from the US [1] suggests we may need our thinking caps on more often.

## Study

The study was part of the US National Heart Failure Project. Hospital charts of patients discharged over the year to March 1999 with a principle diagnosis of heart failure were examined. The goal was to examine 800 discharge charts for each State. When fewer than 800 were available, all were examined. When more than 800 were available, 800 were chosen randomly. The discharge codes used had been shown to have high specificity for heart failure, and this was confirmed in a review of 100 charts by a cardiologist.

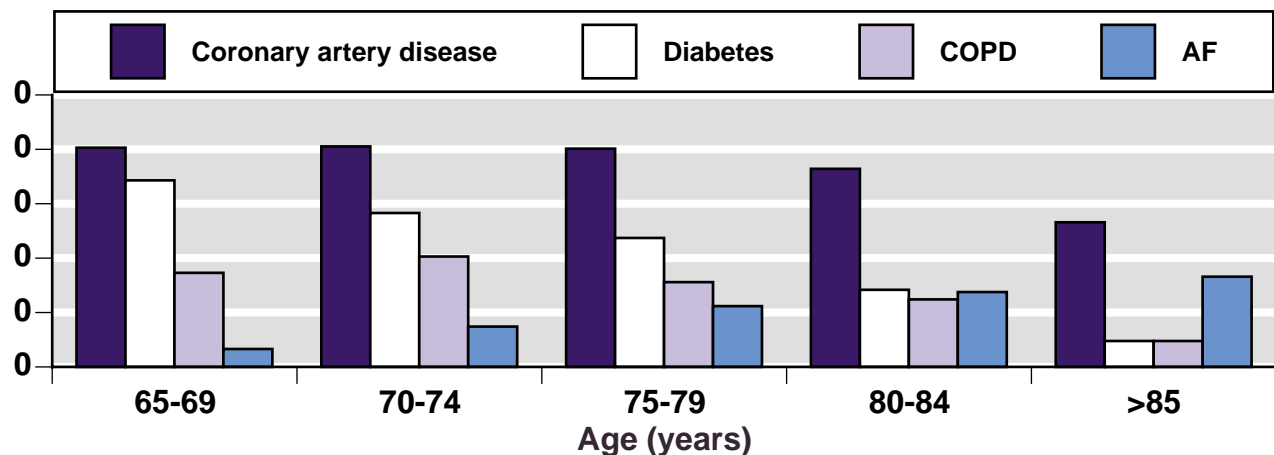
From the charts, 192 items of information were collected, including administrative data and information on history, physical examination and laboratory results.

**Figure 1: Age of 35,000 heart failure patients**



**Figure 2: Co-morbid conditions in heart failure patients, by age**

Percent



## Results

There were 34,587 charts available for patients with a discharge diagnosis of heart failure and who were 65 years or older. The average age was 79 years, and 58% were women. The mean left ejection fraction was 69%, and 31% had a left ejection fraction above 40%.

Other disorders were frequently present. There was a history of hypertension in 61%, coronary artery disease in 56%, diabetes in 38%, COPD in 33%, atrial fibrillation in 30%, history of stroke in 18% and dementia in 9%. About 10% would have a creatinine above 225  $\mu\text{mol/L}$ .

There were important age-related changes across these patients. Firstly, within this restricted age range there were more older than younger patients, with a preponderance of over-85 year olds (27%). The presence of other conditions also varied with age. Though a history of hypertension was static at about 60%, coronary artery disease, diabetes and COPD were less common in over-85s than younger patients, while atrial fibrillation was more common (Figure 2). Dementia rose steadily from 3% in the youngest age group to 16% in over-85s.

## Comment

Now this is a particular sample of patients who have been in hospital, primarily with problems relating to their heart failure. It may not be exactly similar to patients with heart failure who have not been admitted to hospital. But it serves to remind us that elderly patients with heart failure are likely to have co-morbid conditions and poor renal function. Even within the restriction of the over-64s there are age-related differences.

Interpreting the results of clinical trials in the light of this large survey will be interesting. It also impacts on development of guidance for treating older patients with heart failure.

### References:

- 1 EP Havranek et al. Spectrum of heart failure in older patients: results of the National Heart Failure Project. *American Heart Journal* 2002 143: 412-417.

## BOOK REVIEWS

**The desktop guide to complementary and alternative medicine.** E Ernst, MH Pittler, C Stevinson, A White. Mosby, Edinburgh, 2001. more than 400 pp, plus CD-ROM. Price not known. ISBN 0-7234-3207-4.

The problem with complementary and alternative therapy is two fold. First, there is so much of it. Who said "Give me a needle, and I will invent yet another form of acupuncture"? Probably nobody, but most of us feel that way when we read another silly article in the newspapers, or when a patient expects us to know the ins and outs of another herb.

Hands up, who can write a five minute essay on the synonyms, trade names, constituents, background, uses, pharmacological action, conditions treated, clinical evidence, dosage, risks and risk-benefit assessment of Mary thistle? Sneakily, **Bandolier** can.

But that's just because we opened a page at random from this terrific book by Edzart Ernst and his chums. It is a veritable BNF of alternative medicine, but an alternative BNF with evidence.

And there's the rub, evidence. The trouble is that there is too often no evidence for most complementary or alternative therapy. What evidence there is, is in the pages of this book. **Bandolier** is sceptical when it comes to most complementary therapy, having wasted more hours than needed delving in these murky pools. This book makes it easy. If there's no evidence, Ernst tells us so. There are also some choice bits of information, like the link between homeopathy and Naziism.

**Bandolier** doesn't agree with every interpretation, but this is a valuable book for the shelf, and the CD-ROM that accompanies it is a whizz on your computer. It works on Macs above G3 using OS9.

**Management of the menopause. The handbook of the British Menopause Society.** Margaret Rees and David Purdie. BMS Publications, Marlow, 2002. 127pp, £15. ISBN 0-9536228-1-9.

Human females are just about the only mammals with significant post-menopausal survival. This book describes most of the things we are interested in, and describes them well, in accessible language, and with much wisdom.

It takes us in simple steps through physiology, acute symptoms, long-term consequences, treatments, management and assessment and investigations. HRT is obviously examined in great detail, but so are treatments other than oestrogen and even complementary therapies.

The style is direct, uncluttered with references, though each chapter has lists of key references handily structured under particular headings. Readability is only compromised by an occasional reliance on odds ratios and relative risks when absolute risks would be so much more helpful. Knowing the odds ratio for endometrial cancer with HRT is not

as useful than knowing that a small risk is still small. This is balanced by other terrific information, like calcium contents of common foods, or the cause of death in women over 50 years.

Quibbles aside, this is a useful book, not just for the shelf, but to read through and then keep on the shelf, knowing that there's help on hand when you need it. It's a steal at £15. It's accessible to patients as well as professionals.

**The ethics of medical research on humans.** Claire Foster. Cambridge University Press, Cambridge, 2001. 159 pp, price not known. ISBN 0-521-64573-5.

Ethics. It's one of those words that can cause brain ache without really trying. It's so complex, with so many different issues, and with overtones of emotion and belief. Evidence is a much more simple word, as long as we talk about medical evidence, and not a court of law, when evidence can take on the same overtones as ethics in medical research.

Of course we want to be ethical, and we can usually spot what's not ethical, but which of us would react with joy to being asked to serve on a research ethics committee?

For those of us who do, or may, or even aspire to examine the ethics of research, then reading this book is a must. Not because it's easy, because it isn't. That's not Claire Foster's fault, because she does a great job of making us think. It is the nature of the beast. She gives us a framework of three approaches to thinking about ethics: a goal-based approach (moral worth deriving from actual or expected outcome), a duty-based approach (rules of conduct not related to the goals), or a right-based approach (autonomy). She then examines these approaches from first principles, to practice, and through case studies. Importantly the end is a framework for research ethics committees.

Does it work? Well mostly. If there is a problem, it may be in the choice of case studies, where some examples of poor evidence are used to develop thinking. Perhaps it is a good choice, because it makes us think. Perhaps it is a bad choice, because poor evidence clouds the salience of discussions on ethics. Perhaps the fact of thinking makes the point.

No-one serving on an ethics committee should not read this book, and perhaps no-one thinking of submitting a proposal to an ethics committee should not read it too.

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